DETAILED ACTION

Status of claims

Claims 2, 3, 19-21 and 26-30 were cancelled in an amendment filed 11 February 2008. As a result, claims 1, 4-18 and 22-25 are pending and are examined herein on the merits for patentability. No claim is allowed at this time.

Terminal Disclaimer

The terminal disclaimers filed on 11 February disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of U.S. Patent Nos. 6,830,557 and 6,555,508 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Paul '641 (US 2002/0137641).

Paul '641 disclose a liquid foaming soap composition comprising a mixture of surfactants (i.e. polysorbate 20, cocoamide DEA, polysorbate 60, polysorbate 80, ammonium or alkaline salts of sulfated aliphatic alcohols, ammonium or alkaline salts of sulfated aliphatic ethoxylated alcohols, cocoamido derivatives and ethoxylated aliphatic phenolics) in combination with water, and further comprising at least one therapeutic agent (i.e. silver nitrate solutions) (claims 1-6). Paul '641 further disclose the composition being dispensed from a container selected from the group consisting of finger actuated foam producing valve bearing containers and squeeze bottle foam producing containers, wherein the squeeze bottle container further comprises an elongated delivery nozzle formed thereon for enabling insertion thereof into elongated cavities formed in the human body (claims 7-8).

Also, Paul '641 disclose a process for achieving a multi-purpose improved liquid foaming soap delivery system for medicinal benefit comprising forming a foam composition as described above, placing the foam composition into a container described above, and applying the foam mousse to a desired site, such as the cavity of the human body (claims 22-23).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Response to Arguments

Applicants comment on page 11 that Mr. Paul is the sole inventor of the subject matter disclosed in this cited reference and not claimed in this reference. Applicants further comment that they will gladly supply any required affidavit or declaration confirming his sole invention of this subject matter. According to MPEP 715.01(a) the rejection under 35 U.S.C. 102(a) or (e) can be overcome by affidavit or declaration under 37 CFR 1.131 or an unequivocal declaration under 37 CFR 1.132 by Applicant that he/she conceived or invented the subject matter disclosed in the patent or application publication and relied on in the rejection. Therefore, in the absence of an affidavit or declaration under 37 CFR 1.131 or 1.132, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 11-18 and 22-25 are rejected under 103(a) as being unpatentable over James (GB 1,372,721) in view of Wright (US 4,531,659) and Boehm et al. (US 3,422,993).

Applicant claims:

Applicants claim a medicinal delivery system comprising an antibacterial/antiviral/ antimicrobial foam comprising at least one surfactant, at least one therapeutic agent and water, within a non-pressurized, propellant-free container.

Determination of the scope and content of the prior art

(MPEP 2141.01)

James teaches a container of antiseptic for the treatment of burns and scalds by topical application, comprising at least one surfactant, a topically acceptable antiseptic active agent, and water, wherein the container comprises an outlet and valve means operable to allow discharge of the contents in the form of a foam (page 1, lines 26-37), which effectively controls *Pseudomonas aeruginosa* (page 5, lines 14-16). Also, James discloses a surfactant composition comprising cocodimethylamine-N-oxide (page 3, lines 92-96). James further teaches the container comprising silver nitrate solutions

(page 2, lines 95-96 and 113-115; page 4, lines 87-90, 108-110 and 119-120; and claim 14) or silver salt preferably in conjunction with a protective colloid (page 2, lines 68-71).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

It is noted that James teaches the foam composition comprising a pressurizing agent/propellant. However, it was well-known at the time of the invention to formulate foamable compositions in non-aerosol, non-pressurized containers for medicinal delivery. For instance, Wright teaches a foam-producing device (Fig 4 and 7) comprising a squeeze bottle 112 (col. 3, ll. 4-8), and an elongated flexible nozzle 130 (col. 4, l. 44) held in place by a cap 118 threaded to the squeeze bottle 112 (col. 4, l. 39), which facilitates insertion into body cavities to deposit medicinal foam (col. 1, ll. 63-65; col. 2, ll. 1-2; and col. 5, ll. 44-47). Also, Boehm et al. teach that aerosol-based foam containers have several disadvantages, such as the requirement for specialized pressurizing equipment and special valves of close tolerance, the containers must be able to withstand high pressures, the containers cannot be re-used, and there is at least a minimum amount of danger as a result of explosive or fire hazards brought about by the pressurized container and expandable gas (col. 1, l. 61 - col. 2, l. 1).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to incorporate the silver salt composition of James into a non-pressurized, non-aerosol foam producing device, such as the device taught by Wright,

because it is known in the art that medicinal foam compositions can be formulated in non-aerosol containers to avoid certain disadvantages associated with pressurized, aerosol containers, as taught by Boehm et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over James in view of Wright and Boehm et al., as applied to claims 1, 11-18 and 22-25 above, further in view of Ramirez et al. (US 5,254,334).

Applicant claims:

Applicants claim the medicinal delivery system defined in claim 1 wherein the surfactant is between about 0.1 to 30 wt.% sodium lauryl sulfoacetate, sodium lauroyl sarcosinate, or vegetable oil based soap.

Determination of the scope and content of the prior art

(MPEP 2141.01)

James, Wright and Boehm et al. teach foam compositions comprising a silver salt, surfactant and water within a non-pressurized, non-aerosol container.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

James, Wright and Boehm et al. do not teach the surfactant to comprise sodium lauryl sulfoacetate, sodium lauroyl sarcosinate, or vegetable oil based soap, as instantly claimed. However, Ramirez et al. teach foam compositions for topical administration (column 1, lines 7-32), wherein the foam composition comprises glycerin, sodium cocoyl isethionate, sodium lauryl sulfate, emollients, foam boosters, and additives (column 2, lines 32-68). Ramirez et al. also teach that sodium lauryl sulfoacetate and sarcosynates are foam boosters that enhance the foam produced when exposed to water during use (column 2, lines 51-58; and claims 6-8). Ramirez et al. further teach that additional active ingredients such as vitamin A, vitamin E, and antibacterial agents may be incorporated into their foam compositions (column 2, lines 59-68).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use sodium lauryl sulfoacetate and sarcosynates as foam boosters in the foam composition of James because they enhance the foam produced when exposed to water during use, as reasonably taught by Ramirez et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

3. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over James in view of Wright, Boehm et al. and Ramirez et al., as applied to claims 1, 4, 11-18 and 22-25 above, further in view of Grier ("Silver and Its Compounds", Disinfection, Sterilization, and Preservation, 1983, 375-389)

Applicant claims:

Applicants claim the medicinal delivery system defined in claims 1 and 4 wherein the therapeutic agent is colloidal silver in water or silver nanocrystal powder.

Determination of the scope and content of the prior art

(MPEP 2141.01)

James, Wright, Boehm et al. and Ramirez et al. teach foam compositions comprising a silver salt, sodium lauryl sulfoacetate and sarcosynates surfactants and water within a non-pressurized, non-aerosol container.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

James, Wright, Boehm et al. and Ramirez et al. do not teach the silver salt composition to comprise colloidal silver in water or silver nanocrystal powder. However, Grier teaches that silver nitrate, colloidal silver preparations, colloidal metallic silver, and colloidal silver halides all have antimicrobial activity (pg. 375-387).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use silver nitrate, colloidal silver preparations, colloidal metallic

silver, or colloidal silver halides in the antimicrobial foam compositions of James, because they are all known to have antimicrobial activity.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

4. Claims 6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over James in view of Wright, Boehm et al., Ramirez et al. and Grier, as applied to claims 1, 4, 5, 7, 11-18 and 22-25 above, further in view of Burke et al. (US 5,296,215).

Applicant claims:

Applicants claim the medicinal delivery system defined in claims 5 and 7 wherein the sodium lauryl sulfoacetate and sarcosynates are present at between 0.2 to 1.0 wt.% for claim 6 and between 0.5 and 5 wt.% for claim 8. Applicants further claim the medicinal delivery system of claim 8 further comprising 20 to 35 wt.% of propylene glycol or denatured ethanol.

Determination of the scope and content of the prior art

(MPEP 2141.01)

James, Wright, Boehm et al. and Ramirez et al. teach foam compositions comprising a silver salt, sodium lauryl sulfoacetate and sarcosynates surfactants and water within a non-pressurized, non-aerosol container.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

James, Wright, Boehm et al., Ramirez et al. and Grier do not teach the surfactant to comprise 0.2 to 1.0 wt.% or 0.5 to 5 wt.% sodium lauryl sulfoacetate and sarcosynates, as instantly claimed. However, Burke et al. teach that sodium lauryl sulfoacetate is incorporated into a foam composition at about 0.1 to 3 wt.%, preferably 0.3 to 1.5 wt.% (column 3, lines 16-19).

Also, James, Wright, Boehm et al., Ramirez et al. and Grier do not teach the medicinal delivery system to further comprise 20 to 35 wt.% of propylene glycol or denatured ethanol. However, it is well known in the art at the time of the instant invention that humectants can be added to topical foam compositions to improve the feel on the skin. Burke et al. teach 10 to 40 wt.%, preferably 15 to 30 wt.% propylene glycol exemplifies humectants used in foam compositions (column 4, lines 50-58).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use about 0.1 to 3 wt.%, preferably 0.3 to 1.5 wt.% sodium lauryl sulfoacetate and 15 to 30 wt.% propylene glycol in the foam compositions of James et al. because Burke et al. teach that 0.3 to 1.5 wt.% sodium lauryl sulfoacetate and 15 to 30 wt.% propylene glycol as a suitable surfactant and humectant, respectively, for use in foam compositions.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

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